

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-111

BIOEQUIVALENCE

Ipratropium bromide
0.02% Inhalation solution
NDA #75-111
Reviewer: J. Lee
75111W.497

JUL 21 1997

Alpharma
Baltimore, MD
Submission date:
April 11, 1997

Review of a Request for Waiver

The sponsor has submitted an application for ipratropium bromide 0.02% inhalation solution and is requesting a waiver from in-vivo bioequivalence testing for their test product under 21 CFR 320.22 (b)(3). The sponsor has provided a comparison (attached) between their test product and Atrovent® 0.02% inhalation solution (Boehringer Ingelheim) with regard to conditions of use, active ingredient, dosage form, route of administration, and strength.

The drug product is intended for inhalation administration.

A qualitative/quantitative formulation comparison is provided below:

	<u>Alpharma</u> per 2.5 ml	<u>Atrovent</u> per 2.5 ml
Ipratropium bromide		
Sodium chloride		
HCl		
Water for injection		

Comment:

1. The test and reference products are qualitative and quantitatively the same within the guidelines of 'sameness' in OGD's Inactive Ingredients Guide.

Recommendation:

1. The Division of Bioequivalence agrees that the information submitted by the sponsor demonstrates that ipratropium bromide 0.02% inhalation solution falls under 21 CFR 320.22 (b)(3) of Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of an in-vivo bioavailability study be

Section IV

Information demonstrating that the proposed product is the same as the listed product.

	LISTED DRUG	PROPOSED DRUG
	Atrovent® 0.02%	Ipratropium Bromide
	Inhalation Solution	Inhalation Solution, 0.02%
	Boehringer Ingelheim	Alpharma
Conditions of use:	Indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.	
Active Ingredient:	ipratropium bromide	ipratropium bromide
Dosage Form:	solution	solution
Route of Administration:	inhalation	inhalation
Strength:	0.02%	0.02%